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**From:** Mario Lowe [Mario.Lowe@intusurg.com]  
**Sent:** 2/13/2019 10:30:30 AM  
**To:** Lindsey Otradovec [Lindsey.Otradovec@intusurg.com]; Mark Johnson [Mark.Johnson@intusurg.com]  
**CC:** Chace Rawls [Chace.Rawls@intusurg.com]; Katie Scoville [Katie.Scoville@intusurg.com]  
**Subject:** RE: Si service and Instrument reprocessing  
**Attachments:** K182140.Letter.SE.FINAL\_Sent001.pdf; K182140.IFU.FINAL\_Sent001.pdf

Hi Lindsey:

We can certainly provide the latest FDA 510(k) Clearance letters. But this will not provide the information requested in Item 1 below. See attached for an example of an Xi Clearance letter.

The request in item 1 - required limitation of the number of uses per Endo-Wrist Instrument

Can you provide more clarification on what the hospital is looking for?

Just so you know, FDA does not require nor limit the number of uses for our EW instruments. During the 510(k) submission process, we provide data to FDA that supports the stated number of lives for a particular instrument that we state in our labeling.

Mario

Mario Lowe  
Sr. Director, Regulatory Affairs

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**From:** Lindsey Otradovec <Lindsey.Otradovec@intusurg.com>  
**Sent:** Wednesday, February 13, 2019 7:26 AM  
**To:** Mark Johnson <Mark.Johnson@intusurg.com>; Mario Lowe <Mario.Lowe@intusurg.com>  
**Cc:** Chace Rawls <Chace.Rawls@intusurg.com>; Katie Scoville <Katie.Scoville@intusurg.com>  
**Subject:** FW: Si service and Instrument reprocessing

Mark and Mario,

Can you provide me with any of the documentation for #1 below. The Baylor Health system is being very difficult as of late and we are trying to secure a live meeting to discuss things further. I assume you have a pdf file of the Xi and Si certification letters that we can send to them? Need your guidance here.

Any help you can provide would be helpful.

Thank you. Lindsey

**From:** Johnson, Tony <TONY.JOHNSON@BSWHEALTH.ORG>

**Sent:** Tuesday, February 12, 2019 2:03 PM

**To:** Chace Rawls <Chace.Rawls@intusurg.com>; Watson, Janet L <JANET.WATSON@BSWHEALTH.ORG>; Koreneff, Alan <ALAN.KORENEFF@BSWHEALTH.ORG>

**Cc:** John Wagner <John.Wagner@intusurg.com>; Lindsey Otradovec <Lindsey.Otradovec@intusurg.com>; Shelton Sykes <Shelton.Sykes@intusurg.com>

**Subject:** [EXTERNAL] RE: Si service and Instrument reprocessing

Chase,

We look forward to meeting again, however, we feel the meeting will not be productive until we receive the information we have repeatedly requested from Intuitive. Please provide the information below that we have been requesting and we will be happy to meet:

**Information requested by BSWH:**

1. Provide documentation of the latest FDA certifications for Xi and Si robots and proving the FDA granted the 510K based on a required limitation of the number of uses per Endo-Wrist Instrument.
2. Provide documentation proving an FDA requirement to perform a preventative maintenance service to remove the PM recommended notification light.
3. Provide documented scope of what is included in a preventative maintenance service and what is specifically excluded. BSWH does not find any transparency in past and current contracts for Service that define what is included vs excluded.
4. Request for "Distributor Toolkit". Informed by Jason Cooley, Field Service Senior Manager, that it is "Unavailable", although we understand it is available in Europe.
5. Need actual documents noted as "Documentation" in the Master Agreement terms and conditions to be included with the Master Agreement.
6. Provide data pertaining to BSWH cases including surgeon specific data, length of surgery, instruments used and other technical factors to allow BSWH to assess outcomes, efficiencies, etc.
7. Records of maintenance performed to date on all Si and Xi systems. Records should include specific description of preventative maintenance, corrective maintenance and/or any other maintenance performed on each unit including dates of service.

Requests pertaining to Information Services Agreement:

8. Provide documentation showing an express requirement by the FDA that the Si and Xi robots must be re-certified with a security, vulnerability or other software patch before the patch is made available to Intuitive's customers or applied in a production setting
9. A copy of Intuitive's latest independent audit report – (i.e., with regarding to information security on controls within Vendor's organization concerning the privacy, confidentiality, security, processing integrity, and availability of the Products and Services made pursuant to standards established by an authorized or recognized standards setting organization (e.g., International Auditing and Assurance Standards Board; Statement on Standards for Attestation Engagements (SSAE) SOC 1 report; SSAE SOC 2 report; ISO/IEC 27000 series) and prepared by a reputable independent auditing firm)
10. A detailed description and screen capture showing the complete English-language translation of the binary data feed from the robots to Intuitive

Thanks in advance for your prompt response.

**Tony W. Johnson**

Senior Vice President and Chief Supply Chain Officer  
Baylor Scott & White Health

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**From:** Chace Rawls [<mailto:Chace.Rawls@intusurg.com>]

**Sent:** Tuesday, February 12, 2019 11:31 AM

**To:** Johnson, Tony <[TONY.JOHNSON@BSWHEALTH.ORG](mailto:TONY.JOHNSON@BSWHEALTH.ORG)>; Watson, Janet L <[JANET.WATSON@BSWHEALTH.ORG](mailto:JANET.WATSON@BSWHEALTH.ORG)>;

Koreneff, Alan <[ALAN.KORENEFF@BSWHEALTH.ORG](mailto:ALAN.KORENEFF@BSWHEALTH.ORG)>

**Cc:** John Wagner <[John.Wagner@intusurg.com](mailto:John.Wagner@intusurg.com)>; Lindsey Otradovec <[Lindsey.Otradovec@intusurg.com](mailto:Lindsey.Otradovec@intusurg.com)>; Shelton Sykes <[Shelton.Sykes@intusurg.com](mailto:Shelton.Sykes@intusurg.com)>

**Subject:** {EXTERNAL} Re: Si service and Instrument reprocessing

All,

I just wanted to follow up and see if there is a time we could meet next week with our Service leadership as requested below. We continue to have a lot of issues being bubbled up to our Field Service team, and I just want to ensure we are all aligned appropriately. Let me know if there is a date/time that works for you all.

Thanks so much!

Chace Rawls  
Director, Academic Key Accounts  
South Central United States  
*Intuitive Surgical, Inc*  
Cell: 469-223-8350  
E-mail: [Chace.Rawls@intusurg.com](mailto:Chace.Rawls@intusurg.com)

On Feb 6, 2019, at 4:33 PM, Chace Rawls <[Chace.Rawls@intusurg.com](mailto:Chace.Rawls@intusurg.com)> wrote:

All,

I hope this e-mail finds you all doing well.

During our meeting on Jan 15th, where we discussed the service contracts, we agreed to have some follow up discussions around our role in servicing your Si's. Since that time, it has also been brought to our attention that there have been some decisions made around reprocessing the instruments and replacing the chips that limit instrument lives.

While we understand that there is a need to control cost as much as possible, there are also some risks that should be considered. This topic has also come up as we negotiate the Master Agreement as there is language in that agreement specific to instrument usage. Given the critical nature and potential risk implications in these scenarios, I wanted to see if we could schedule a meeting to bring our VP of Field Service to Baylor and talk

through all of these issues together. At the end of the day, our goal is to ensure that all considerations are being factored into the decision and that BSWH isn't exposed to unforeseen risks.

John Wagner is our VP of Field Service, based out of California. He is available to come to Dallas between Feb 19-21. Let me know if there is a time on any of those days that you all would be available to meet, and I will coordinate on our end

Thanks so much!

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